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April 1, 1999

Patricia Y. Love, M.D., Director (HFD-160)
Division of Medical Imaging and Radiopharmaceutical
Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
Food and Drug Administration
Parklawn Building, Room 18-B-09
5600 Fishers Lane
Rockville, Maryland 20857

Re: Draft "Guidance for Industry: Developing Medical Imaging Drugs And Biologics" (Docket No. 98D-0785)

Dear Dr. Love:

Attached is a joint letter from Mark Carvlin of the Medical Imaging Contrast Agent Association and Robert Morgan of the Council on Radionuclides and Radiopharmaceuticals. The letter requests that FDA reissue the above referenced guidance in draft form for further, abbreviated comment rather than finalizing it at this stage.

If you have any questions about the attached letter, please direct them to me.

Sincerely,

Richard C. White

cc: Jane A. Axelrad, Esq. (by facsimile)
Rebecca A. Devine, Ph.D. (by facsimile)
George Q. Mills, M.D. (by facsimile)
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98D-0785 C11

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Re: Draft "Guidance for Industry: Developing Medical Imaging Drugs And Biologics" (Docket No. 98D-0785)

Dear Dr. Love:

We are writing on behalf of the Medical Imaging Contrast Agent Association (MICAA) and the Health Care Committee of the Council on Radionuclides and Radiopharmaceuticals (CORAR) regarding FDA's procedure for finalizing the above referenced Guidance. At the FDA-industry meeting on the Guidance held on March 26, 1999, FDA's issue updates and the subsequent discussion of these issues indicated that the Guidance might be substantially revised and/or expanded in certain areas, including the procedure and criteria for Group 1 designation, requirements for pharmacokinetic studies, timing of other non-clinical studies, and the roles of independent blinded and informed readings and their use in the labeling. FDA also indicated that clarifications will be added in a number of other areas. In view of the anticipated changes, we request that, rather than finalizing the Guidance at this stage, FDA reissue the Guidance in draft form for further, abbreviated comment.

Issuing a new draft would have a twofold benefit. First, it would permit interested parties to review and provide useful comments on substantially revised portions of the Guidance. FDA's discussion at the meeting of possible changes, while informative, was too general to permit any detailed comment in the absence of a new draft. Second, a redraft with comment period would generally help to ensure that the language used in the final Guidance is understood and interpreted consistently by all interested parties, and that FDA's clarifications have achieved their purpose. MICAA and CORAR expect to submit their comments on the current draft by April 14, so that FDA can consider them before issuing the next version of the Guidance. If the Guidance is issued as a redraft, as requested, we would

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anticipate that an abbreviated comment period – for example, 30 days – would be sufficient, since the major comments of MICAA, CORAR, and other interested parties would already have been submitted.

On behalf of MICAA and CORAR, we wish to thank you and your colleagues at FDA for your willingness to spend considerable time meeting with us to exchange views on the development and review of medical imaging drugs. We believe that these exchanges have been very fruitful, and we hope they will assist FDA in developing this important Guidance.

Sincerely,

Mark Carvlin
Chairman, Regulatory Policy Committee
Medical Imaging Contrast Agent Association, Inc.

Robert A. Morgan
Chairman
Council on Radionuclides and Radiopharmaceuticals, Inc.